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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/308,218	09/19/1994	MARC ALIZON	3495.001019	4831

22852 7590 02/13/2004

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/308,218	ALIZON ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.129(a)

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on November 19, 2003 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 14-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches nucleic acid probes of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

Chang expressly teaches formation of expression vectors, including an E. coli expression library which would contain every open reading frame (see column 5, line 66 to column 6, line 12).

Chang expressly teaches mammalian and yeast vectors (see column 6, lines 9-13).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

Chang teaches methods of expression and making recombinant DNA molecules (see columns 5 and 6).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides claimed are presented below.

```
Query:                                        gacagggcttggaaaggattttgctataaga 8153
                                              ||||||||||||||||||||||||||||||
Sbjct:                                        gacagggcttggaaaggattttgctataaga 8354
orfF   1                                       D  R  A  W  K  G  F  C  Y  K
env    851    A  I  R  H  I  P  R  R  I  R  Q  G  L  E  R  I  L  L ^^^

Query: 8154 tgggtggcaagtggtcaaaaagtagtgtggttggatggcctgctgtaagggaaagaatga 8213
             ||||||||||||||||||||||||||||||||||||||||||| ||||||||||||||||
Sbjct: 8355 tgggtggcaagtggtcaaaaagtagtgtggttggatggcctactgtaagggaaagaatga 8414
orfF   11   M  G  G  K  W  S  K  S  S  V  V  G  W  P  T  V  R  E  R  M

Query: 8214 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctagaaaaacatg 8273
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                |||||||||||||||||||||||||||||||||||||||||||||||||||||||||| ||||||||||
Sbjct: 8415 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctggaaaaacatg 8474
orfF   31   R  R  A  E  P  A  A  D  G  V  G  A  A  S  R  D  L  E  K  H


Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333
              |||||||||||||||||| |||||||||| |||||||| ||||||||||||||||||| 
Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcac 8534
orfF   51   G  A  I  T  S  S  N  T  A  A  T  N  A  A  C  A  W  L  E  A


Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393
              |||||||||||||||||||||||| ||||||||||||||||||||||||||||||||| 
Sbjct: 8535 aagaggaggaggaggtgggttttccactcacacctcaggtacctttaagaccaatgactt 8594
orfF   71   Q  E  E  E  E  V  G  F  P  L  T  P  Q  V  P  L  R  P  M  T


Query: 8394 acaaggcagctgtagatcttagccacttttaaaagaaaaggggggactggaagggctaa 8453
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||| 
Sbjct: 8595 acaaggcagctgtagatcttagccacttttaaaagaaaaggggggactggaagggctaa 8654
orfF   91   Y  K  A  A  V  D  L  S  H  F  L  K  E  K  G  G  L  E  G  L


Query: 8454 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||| 
Sbjct: 8655 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714
orfF   111  I  H  S  Q  R  R  Q  D  I  L  D  L  W  I  Y  H  T  Q  G  Y


Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573
              ||||||||| |||||||||||||||||||||| |||||||||||||||||||||||| 
Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774
orfF   131  F  P  D  W  Q  N  Y  T  P  G  P  G  V  R  Y  P  L  T  F  G


Query: 8574 ggtgctacaagctagtaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633
              |||||||||||||||||||||||||||||| ||| ||||||| ||||| |||||||||| 
Sbjct: 8775 ggtgctacaagctagtaccagttgagccagataaggtagaagaggccaataaaggagaga 8834
orfF   151  W  C  Y  K  L  V  P  V  E  P  D  K  V  E  E  A  N  K  G  E


Query: 8634 acaccagcttgttacaccctgtgagcctgcatggaatggatgacccggagagagaagtgt 8693
              |||||||||||||||||||||||||||||||||||||||||||||||||||| |||||||||||| 
Sbjct: 8835 acaccagcttgttacaccctgtgagcctgcatggaatggatgaccctgagagagaagtgt 8894
orfF   171  N  T  S  L  L  H  P  V  S  L  H  G  M  D  D  P  E  R  E  V


Query: 8694 tagagtggaggtttgacagccgcctagcatttcatcacatggcccgagagctgcatccgg 8753
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||| 
Sbjct: 8895 tagagtggaggtttgacagccgcctagcatttcatcacgtggcccgagagctgcatccgg 8954
orfF   191  L  E  W  R  F  D  S  R  L  A  F  H  H  V  A  R  E  L  H  P


Query: 8754 agtacttcaagaactgc
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                ||||||||||||||||||
Sbjct: 8955 agtacttcaagaactgc
orfF   211  E  Y  F  K  N  C ^^^
```

It is noted that with regard to, for example, the sequence region between shown above, there are 14 nucleotide differences between the sequences, yielding about a 2% error rate. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

With regard to the kit claims, it is noted that the preamble phrase "a kit" imposes no structural requirements upon the product claims.

Response to Arguments

4. Applicant's arguments filed November 19, 2003 have been fully considered but they are not persuasive.

Applicant argues that the sequence of Chang was more carefully performed than the raw sequence analysis of Richterich, because the sequence was "polished". This refers to a term of art in which the sequence is repeatedly checked for accuracy. However, the issue in the current case is simply one of fact. Are the sequences the same or not? The examiner has read portions of John Crewdson's book "Science Fictions", which discusses the original studies on HIV in 1984. Crewdson quotes Wong-Staal, a coinventor on the Chang patent, as saying "that LAV and HTLV-3 are

independent isolations of the same virus (see page 165)." Crewdson further notes "They had come from the same patient (see page 165)."

Further, Applicant specifically argues that Chang performed careful analysis. This is entirely belied and contradicted by Crewdson, who notes "The gene map of ARV, decoded by Paul Luciw and his California team, was a dead match for LAV, which meant Gallo's map was dead wrong (see page 173)." So contrary to Applicant's arguments, there was not significant care taken by Chang's group. At note s, on page 565, Crewdson writes, "The Gallo group had sequenced two clones of HTLV-3B. The first didn't appear to have the fifth gene but the second did. Or did it? Because HTLV-1 didn't have five genes, the prevailing opinion in Gallo's lab was that the AIDS virus didn't either and what looked like a fifth gene was an artifact." This further supports erroneous sequencing by Gallo, since at least once they failed to find an entire gene. This would be rather difficult to explain in a careful sequencing project.

So Applicant's entire argument rests on the supposition, without evidence, that the sequences were carefully performed.

Applicant's other argument is that Ratner resequences BH10. This is not correct. In reading Ratner's paper, there is no evidence that Ratner resequenced BH-10. Ratner simply compared a different clone to BH-10. At page 63, bottom of the page, Ratner states "The previously sequenced clone BH10 (28)", referring to reference 28, which is the original 1985 Nature paper and not some later resequencing. So, in fact, Ratner does NOT support applicant's position.

As a final point, it is noted that in this case, there is better evidence than is ordinarily available that the strains sequenced by the two different groups are, in fact, the same since it is clear that the LAI strain is common to both of these applications. There is express evidence, as discussed above, that the viruses were the same.

Since the evidence of record does not support Applicant's position, the rejections are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1634